

Congress of the United States

Washington, DC 20510

October 20, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

We write to you with concern regarding the nation's supply of vaccines to protect the American people against the threat of smallpox. Disturbing recent news reports¹ indicate that in recent years the Strategic National Stockpile's (SNS) supply of smallpox vaccines for immunocompromised patients – which can also be used to prevent monkeypox – dwindled to almost zero.

This summer's monkeypox outbreak revealed the Department of Health and Human Services' (HHS) failure to replenish these expiring smallpox doses. This has left the United States scrambling to secure enough doses of JYNNEOS needed for patients during this summer's monkeypox outbreak.

This failure of preparedness also raises critical questions about the status of our current stockpile – including that of smallpox vaccines for the rest of the U.S. population. As recently as October 17, 2022, the Government Accountability Office (GAO) released a report detailing concerns over how the “SNS contained most medical countermeasure types recommended, but often not in the recommended quantities².”

It is important to note that unlike monkeypox, smallpox has a 30 percent mortality rate³ and is considered by the U.S. intelligence community to be one of the most significant biological threats we face. The Department of Homeland Security (DHS) also issued a Material Threat Determinization for smallpox in 2004⁴.

While smallpox was declared eradicated in 1980, the virus continues to exist in research laboratories around the world and remains one of the deadliest bioweapons that can be synthetically developed.

¹ *Before monkeypox outbreak, U.S. officials knew for years they didn't have enough of key shot.* (Aug. 18, 2022). POLITICO. Retrieved October 1, 2022, from <https://www.politico.com/news/2022/08/18/u-s-officials-knew-for-years-they-did-not-have-enough-jynneos-vaccine-00052694>

² *HHS Should Address Strategic National Stockpile Requirements and Inventory Risks.* (Oct. 17, 2022). In U.S. Government Accountability Office (GAO-23-106210). U.S. Government Accountability Office. Retrieved October 17, 2022, from <https://www.gao.gov/assets/gao-23-106210.pdf>

³ History of Smallpox | Smallpox | CDC. (n.d.). Retrieved September 29, 2022, from <https://www.cdc.gov/smallpox/history/history.html>

⁴ Project BioShield: Linking Bioterrorism Threats and Countermeasures Procurement to Enhance Terrorism Preparedness. (October 1, 2022). In *House Committee on Homeland Security - Subcommittee on Emergency Preparedness, Science and Technology*. <https://www.govinfo.gov/content/pkg/CHRG-109hhr27217/html/CHRG-109hhr27217.htm>

Preparedness against smallpox in the United States relies on a foundational strategy of ensuring our stockpile has enough unexpired supply for the entire population. Emergency vaccination is the primary means for controlling the spread of smallpox in the event of a biological attack or accidental release.

As you know, after stockpiling 285 million doses of smallpox vaccine⁵ (ACAM2000) between 2001 and 2007, a large portion of these doses have now expired. Beginning in 2017, doses of ACAM2000 in the SNS began to expire based on the vaccine's 16-year shelf life. HHS has indicated there are now approximately 100 million doses left in the SNS⁶, with more doses expiring each year. Yet Congress has been told repeatedly the United States is prepared to respond to a large-scale smallpox event.

Please respond to the following questions no later than November 21, 2022:

1. How many doses of JYNNEOS and ACAM2000 stockpiled by the SNS have expired and not been replenished?
2. What is HHS' and the Administration for Strategic Preparedness and Response's (ASPR) timeline to exercise contract options on JYNNEOS and ACAM2000 to replenish the stockpile?
3. What is ASPR's plan to ensure we're fully prepared to respond in the event of smallpox attack or outbreak?
4. How does ASPR plan to communicate this plan to Congress, its industry partners and the American people?

Thank you for your attention to this urgent matter.

Sincerely,



Darrell Issa
Member of Congress



Richard Hudson
Member of Congress

⁵ *Acambis wins new contract to supply 155 million doses of smallpox vaccine.* (n.d.). CIDRAP. Retrieved October 1, 2022, from <https://www.cidrap.umn.edu/news-perspective/2001/11/acambis-wins-new-contract-supply-155-million-doses-smallpox-vaccine>

⁶ Assistant Secretary for Public Affairs (ASPA). (Aug. 17, 2022). HHS Orders 2.5 Million More Doses of JYNNEOS Vaccine For Monkeypox Preparedness. HHS.gov. Retrieved October 10, 2022, from <https://www.hhs.gov/about/news/2022/07/01/hhs-orders-2-point-5-million-more-doses-jynneos-vaccine-for-monkeypox-preparedness.html>

